IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 4:17-cv-16
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Plaintiffs hereby move on an emergency basis for a temporary restraining order and preliminary injunction against Defendants pursuant to Federal Rule of Civil Procedure 65, to prevent Defendants from implementing or enforcing the Interim Final Rule, published at 81 Fed. Reg. 90,211 (Dec. 14, 2016), titled *Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment*. The Rule—which was issued without notice-and-comment—is scheduled to go into effect **on January 13, 2017**. The standards for a temporary restraining order and preliminary injunction are satisfied here because Plaintiffs are likely to prevail on their procedural and substantive challenges to the Rule; Plaintiffs will suffer serious and irreparable harm absent preliminary relief; the balance of equities favors preliminary relief; and such relief would advance, not disserve, the public interest.

Plaintiffs have notified Defendants of this request, but Defendants have not consented to this relief. Defendants respectfully request the establishment of a due date for the filing of Defendants' opposition brief by 12:00 noon local time on Wednesday, January 11, 2017. Plaintiffs consent to Defendants' request.

Plaintiffs therefore respectfully request this expedited briefing schedule and, if desired by the Court, a hearing on their motion with sufficient time to permit relief to be entered **before January 13, 2017**. For the reasons explained below, Plaintiffs are entitled to a temporary restraining order and preliminary injunction.

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INTRODUCTION

In a transparent effort to ensure its regulation takes effect before a new administration takes office, the Department of Health and Human Services ("HHS") on December 14, 2016, announced a sea-changing rule without any notice or comment—making it effective on an expedited basis on January 13, 2017—upending twenty years of HHS guidance governing the way in which End Stage Renal Disease ("ESRD") patients obtain health insurance coverage that is necessary to ensure life-sustaining care. *See Interim Final Rule with Comment Period, Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third-Party Payment*, 81 Fed. Reg. 90,211 (Dec. 14, 2016) ("Rule" or "Interim Final Rule") (Seibman Decl. Ex. 1).[1]

If permitted to take effect, the Rule will cause immediate and irreparable harm to patients who are among the most vulnerable in society: ESRD patients who require routine dialysis treatments or transplants to survive. For twenty years, HHS has consistently affirmed guidance permitting ESRD patients to obtain financial assistance from charitable organizations to secure the public or private health-insurance coverage enabling access to life-sustaining care. The Rule reverses that paradigm with no warning, requiring dialysis providers, within thirty days of the Rule's announcement, to make disclosures to and seek permission from insurance companies for these sick patients to continue to receive charitable premium assistance. The Department's about-face will dramatically disrupt thousands of patients' ability to obtain private insurance, interfering with and potentially compromising outright their access to life-sustaining medical treatment while remarkably imposing greater healthcare costs on many patients and their

[1] The Seibman Declaration is attached as Exhibit A. Plaintiffs have not highlighted exhibits because they are relying on the entire documents, and therefore highlighting is not required by Local Rule 7(b).

families. At the same time—with no offsetting benefits to patients—the Rule will impose significant and unrecoverable costs on dialysis providers, and threaten the economic viability of many dialysis facilities, potentially leading to facility closures that will damage providers and patients alike.

As the Rule's history and extraordinary timing make clear, HHS's true motive is to shift hundreds of millions of dollars in health-care costs from private insurers to taxpayers, making it more attractive for those insurers to offer qualified health plans (or "QHPs") under the Affordable Care Act ("ACA") (colloquially known as "Obamacare"). That objective, however, could not possibly have satisfied the demanding "good-cause" showing required by the Administrative Procedure Act ("APA") to implement a rule without notice-and-comment. For that reason, HHS purported to rationalize its Rule and emergency, pre-Inauguration Day implementation as necessary to prevent harm to ESRD patients. Those patient-harm claims collapse upon inspection. In fact, overwhelming evidence, logic, and common sense compel the conclusion that the Rule will create the very harms, including disruptions in coverage to care, that it is purportedly designed to prevent.

Because HHS's rush to enact its Rule without the benefit of notice-and-comment, and to put into effect a midnight rule before a new administration takes over, violates the APA in multiple respects, and because it would impose serious, discriminatory, and irreparable harm on thousands of ESRD patients—many of whom are members of Plaintiff DPC here—and on dialysis providers, the Court should grant this motion for an emergency temporary restraining order and preliminary injunction against the Rule's enforcement.[2]

[2] Counsel for Plaintiffs notified HHS of this motion, and HHS did not consent to the requested relief. Because Plaintiffs have provided notice of their request for a temporary restraining order, the Court may treat the motion as one for a preliminary injunction. *E.g.*, 11A Wright & Miller,

BACKGROUND

I. TREATMENT OF ESRD PATIENTS

ESRD is the last stage of chronic kidney disease. A person suffering from ESRD will die without regularly administered kidney dialysis or a kidney transplant. Ex. B ¶¶ 3-4 (Dialysis Patient Citizens Decl.); Ex. C (DaVita Inc. Decl.) ¶ 9; Ex. E ¶ 81 (Fresenius Medical Care Decl.); Ex. F (U.S. Renal Decl.) ¶ 7. Dialysis is a process of cleaning the blood and removing excess fluid from it, essentially simulating working kidneys, which is accomplished using specialized equipment in a specialized facility. Ex. B ¶ 3; Ex. C ¶ 10, Ex. E ¶ 15. Dialysis treatment is expensive. Each treatment typically lasts about four hours, and must be done three times per week. Ex. B ¶ 3; Ex. C ¶ 10. Paying those costs is out of reach for most Americans, requiring some form of insurance to pay the bills. But ESRD patients are particularly vulnerable, because they are sick and they disproportionally have extremely limited means. Ex. B ¶¶ 7, 38 (55% of DPC members were employed when they started on dialysis, but only 8% of those now on dialysis are still employed full time); Ex. D (American Kidney Fund Decl.) ¶ 15 (70% of clients are unemployed). ESRD also disproportionately affects minorities. Ex. B ¶ 7; Ex. C ¶¶ 9-12 (ESRD is 3.5 times more prevalent in African-Americans than Caucasians).

Congress has long recognized the importance of ensuring that ESRD patients have access to life-sustaining health insurance, while affording such patients meaningful options to elect the coverage that best serves each patient's health and financial needs. In 1972, Congress amended the Social Security Act to make ESRD patients under the age of 65 eligible for Medicare. *See* 42 U.S.C. § 426-1(a). But Congress did not *require* these ESRD patients to enroll in Medicare or

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Federal Practice & Procedure § 2951 (3d ed.). Alternatively, the Court could grant the temporary restraining order and set a date for a preliminary injunction hearing. However the Court proceeds, Plaintiffs respectfully submit that it is imperative that the Rule be enjoined from taking effect on January 13, 2017.

any other public option. Indeed, ESRD is one of the very few disease states that Congress consistently has carefully regulated through extensions of the Medicare Secondary Payer period.

For many ESRD patients under age 65, electing commercial insurance coverage over government insurance affords them superior access to health care at a lower cost. For example, Medi-Gap assists Medicare enrollees with out-of-pocket expenses—which, due to Medicare's requirement that patients pay 20% coinsurance of treatment costs (among other out-of-pocket costs), can be substantial (thousands of dollars), Ex. C ¶ 51—but in 23 states Medi-Gap is not available to ESRD patients under 65. Ex. B ¶ 30; Ex. C ¶ 22; Ex. D ¶¶ 33-37; Ex. E ¶ 30.b; Ex. F ¶¶ 18-19. Nor are ESRD patients under 65 typically eligible for Medicare Advantage plans, which combine the coverage of the different parts of Medicare under a single plan. Ex. C ¶ 20.

ESRD patients on government insurance may likewise suffer reduced access to care for themselves and their families. For patients at any age, coverage under Medicaid—the public health insurance program governed by the States—is typically far more limited than Medicare and private insurance. Ex. B ¶¶ 24, 33, 36; Ex. C ¶ 23; Ex. D (American Kidney Fund Decl.) ¶ 50. In addition, many health-care providers are increasingly refusing to accept new Medicaid patients. Ex. B ¶ 33; Ex. C ¶ 58. QHPs allow patients to provide coverage for their families. Medicare, by contrast, does not cover family members, a particular concern to ESRD patients under 65 who are more likely to have minor children and Medicare-ineligible dependents than older patients. *E.g.*, Ex. B ¶ 55; Seibman Decl. Ex. 2 (American Kidney Fund RFI Resp.) 13.

Given the expense of ESRD treatment, charitable organizations—most notably American Kidney Fund ("AKF")—have long provided premium assistance to eligible ESRD patients. Ex. D ¶¶ 3-8. ESRD patients on either a government or a private plan may receive assistance, and grants are offered based on financial need. Ex. D ¶¶ 5, 20-26, 102(d). The majority (more than

60%) of those benefitting from charitable premium assistance use the funds to pay Medicare insurance premiums or the substantial costs of health-care Medicare does not cover. Ex. D ¶ 21.

Dialysis providers have long been committed to providing financial support to the AKF's premium assistance program. Ex. C ¶ 42; Ex. E ¶ 37. In 1997, the AKF and six unnamed providers obtained from the HHS Office of Inspector General ("OIG") an advisory opinion establishing that, if certain conditions are met, dialysis providers could make contributions to AKF without triggering certain statutory penalties. *See* Advisory Opinion No. 97-1, Office of Inspector General, Dep't of Health and Human Services at 5 (1997) (Seibman Decl. Ex. 3). The conditions include prohibitions on a dialysis provider disclosing to patients that it makes charitable contributions or suggesting to AKF that any contribution should be directed to a particular beneficiary or group of beneficiaries—a prohibition that the Interim Final Rule inexplicably requires providers to violate. *See infra* pp. 23-24. Further, the conditions of the 1997 opinion require AKF to provide assistance to patients whether or not they are being treated at facilities that contribute.[3] This guidance has provided the framework for the provision of charitable premium assistance to ESRD patients for two decades. *See* Ex. D ¶¶ 96-102.

II. HHS TAKES POST-ACA REGULATORY ACTIONS WITH RESPECT TO THIRD-PARTY PREMIUM ASSISTANCE

After the enactment of the ACA, insurers increasingly expressed concern with the fact that third-party assistance was enabling seriously ill—and thus expensive-to-insure—patients to acquire private coverage through QHPs. Ex. D ¶ 80. Concerned that insurers facing increased

[3] In subsequent years the OIG has issued additional opinions addressing the permissibility of various arrangements under which insurance premiums are paid by charitable organizations, including arrangements where donations to such charitable organizations have been made by providers. *E.g.*, Adv. Ops. 15-17, 07-18, 07-06, 06-13, 06-09, 06-04, 02-1, 01-15; *see also Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120 (May 30, 2014); *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623 (Nov. 22, 2005).

cost might abandon the ACA Exchanges, HHS expressed "significant concerns" in a November 4, 2013 Frequently Asked Question ("FAQ response") about "hospitals, other healthcare providers, and other commercial entities" supporting QHP premium and cost-sharing obligations, "because it could skew the risk pool and create an unlevel field in the Marketplaces." HHS mentioned no concerns about patient health. HHS, *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces* (Nov. 4, 2013).[4]

As insurers in response began refusing payment from federal, state, and government-protected programs and grantees, however, HHS revised its position. On February 7, 2014, it issued additional FAQs responses stating that the earlier FAQ response did not apply to premium and cost-sharing payments on behalf of QHP enrollees made by Indian tribes and organizations, or state and federal government programs or grantees, such as the Ryan White HIV/AIDS Program. HHS, *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces* (Feb. 7, 2014).[5] Nor did the earlier FAQ response apply to payments from private, not-for-profit foundations "if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status." *Id.*

When insurers continued to refuse payment, HHS published a rule *requiring* issuers offering individual market QHPs to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; Indian tribes, tribal organizations, or urban Indian organizations; and state and federal government programs. This requirement does not

[4] *Available at* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf.

[5] *Available at* https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf.

apply to not-for-profit charitable organizations. 79 Fed. Reg. 15,240 (March 19, 2014); 45 C.F.R. § 156.1250; *see also* Ex. D. ¶¶ 56-60 (providing additional context on this rule).

On August 16, 2016, HHS issued a request for information ("RFI") regarding concerns that health care providers or others were "offering premium and cost-sharing assistance in order to steer people eligible for or receiving Medicare and/or Medicaid benefits to [QHPs] for a provider's financial gain." *Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans*, 81 Fed. Reg. 57,554, 57,556 (Aug. 23, 2016) (Seibman Decl. Ex. 4). HHS expressed concern that this practice, if it exists, "not only could raise overall health system costs, but could potentially be harmful to patient care and service coordination because of changes to provider networks and drug formularies, result in higher out-of-pocket costs for enrollees, and have a negative impact on the individual market single risk pool (or the combined risk pool in states that have chosen to merge their risk pools)." *Id.* at 57,554. Notably, two of these articulated concerns related to patients, while the other two related to systemic concerns—overall costs and risk pools—under the ACA. HHS stated that the RFI was for "information and planning purposes" only. *Id.* at 57,555. It did not propose new rules.

HHS received 829 responses to the RFI. Dozens of ESRD patients wrote personal letters explaining the value of charitable premium assistance and urging HHS to continue to permit the use of charitable premium assistance. Sixteen different patient advocacy organizations and charities, including AKF, explained the critical importance of their programs to patients and the rigorous controls in place to prevent steering and comply with the OIG guidance. Eighteen providers explained the benefits of such payments to patients, while also recognizing that any improper steering should be eliminated. On the other side, fifteen insurance companies

responded, urging HHS to end premium assistance. The social workers who responded came out on both sides, some supporting premium assistance and others urging greater transparency to patients.[6]

III. AFTER THE NOVEMBER ELECTION, HHS ISSUED AN "EMERGENCY" MIDNIGHT RULE

On November 8, 2016, Donald Trump was elected President, with his administration to take office on January 20, 2017. Weeks later, and despite being aware of the current paradigm for years, HHS suddenly and without notice and comment issued its Rule—contradicting its previously issued guidance—and set an effective date of January 13, only a week prior to the start of the new administration. At the same time, HHS sought comment on the Interim Final Rule as well as other potential changes. *E.g.*, 81 Fed. Reg. at 90,226. Although the RFI had sought information about all third-party premium and cost-sharing assistance, the Rule applies to kidney-dialysis providers alone.

The Rule amends "Conditions for Coverage" ("CfCs")—a set of rules governing dialysis providers' treatment of ESRD patients—to impose on providers' disclosure requirements aimed at helping insurance companies drive ESRD patients off QHPs. The Rule's requirements are poorly thought-through and ill-defined and will have immediate negative effects on ESRD patients. The Rule applies to any provider that "make[s] payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization …, or through another entity." 81 Fed. Reg. at 90,227. The Rule's breadth is staggering, because it applies not only to providers who directly support patients' premium payments; not only providers who contribute to organizations "that make[] a financial contribution to another organization[] that is able to use the funds to make payments of premiums for individual market

[6] All comments are available at https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=CMS-2016-0145&refD=CMS-2016-0145-0002.

plans"; but, indeed, to any provider "that makes contributions through a third party that in turn contributes to an entity that is able to use the contribution to make third party premium payments." *Id*. at 90,219 n.16.

Among required disclosures to patients, the Rule requires providers to disclose to patients that they are contributing to charities like the American Kidney Fund, a required disclosure inconsistent with the 1997 OIG guidance. The Rule then imposes on such providers disclosure requirements expressly aimed at helping insurance companies drive ESRD patients off QHPs. It requires that a covered provider must disclose to insurers every policy that will be paid for, wholly or in part, through premium assistance paid by organizations to which the provider donates. The Rule does not say whether a provider may rely on its current knowledge of patients' use of premium assistance, whether it must actively solicit that information from patients, whether it must attempt to collect this information from organization to which it donates, or whether it must take other steps to obtain this information. A provider must then "[o]btain assurance" from each insurer that it will accept such payments for the plan year. And if insurers do not provide such assurances, the provider must "take reasonable steps" to ensure such payments are not made by the provider or by charitable organizations to which the provider contributes. Indeed, the Rule does not require that the insurer ever respond to a request. Moreover, the Rule does not describe what would constitute "reasonable steps," nor does it explain how a provider is to identify beneficiaries without violating the OIG prohibition on disclosing to patients that the provider "ha[s] contributed to AKF." Seibman Decl. Ex. 3 at 4. As a result, the insurers were provided with complete power to indefinitely delay or deny the patient or the provider's ability to comply. With limited exceptions, failure to comply with CfCs results in termination from Medicare. *See* 42 C.F.R. § 488.604; 42 U.S.C. § 1395rr(g)(1).

In purpose and effect, the Rule's insurer-disclosure obligations will drive ESRD patients to Medicare/Medicaid coverage—or deprive them of coverage altogether—by identifying patients receiving premium assistance and allowing insurers to decline coverage of such individuals. Ex. B ¶¶ 14-15, 37-48; Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-115; Ex. E ¶ 75-78, 80. HHS concedes there is a "significant risk" that insurers will refuse to accept premiums from ESRD patients paid in part through charitable premium assistance when the insurer is informed of that fact. 81 Fed. Reg. at 90,217. Indeed, HHS itself assumes that 50% of patients currently receiving premium assistance will end up shifting to Medicare/Medicaid. *Id.* at 90,226. Further, HHS itself estimates that the cost to dialysis providers of complying with the burdensome requirements that the Rule imposes will be at least $32 million the first year and $28 million for subsequent years. *See id.* at 90,223.

Instead of providing an opportunity for public stakeholder comment on this significant regulatory change, as HHS was required to do under the APA and Medicare Act, the agency invoked the emergency good-cause exception, claiming that a health-related emergency made it necessary to upend an established paradigm that has existed for nearly twenty years. HHS also cut short the 60-day period from publication to effective date required under the Congressional Review Act, making the Rule effective on January 13, 2017, just 30 days after publication. Both procedural maneuvers were necessary—and quite obviously intended—to put a new rule into

effect before the incoming administration would as a matter of course suspend it as a pending midnight regulation.[7]

STANDARD OF REVIEW

Under the APA, the Court "shall hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (B). This Court's "review of the agency's legal conclusion of good cause," so as to avoid the APA's notice-and-comment requirements, "is *de novo*." *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014). If those legal requirements are not met, the court must vacate the Rule. *Id.* at 710.[8]

In addition, agency action "is arbitrary and capricious," when, among other things, an agency "entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to … the product of agency expertise." *Luminant Generation Co., LLC v.*

[7] Outgoing administrations often have substantial incentives to engage in "midnight rulemaking"—attempting to rush through significant regulatory changes consistent with their own political objectives or policy views before a new administration, with different objectives and perspectives, comes to power. CRS, *Midnight Rulemaking* 3 (July 18, 2012). Incoming administrations also regularly take steps to guard against such midnight rulemaking, but their ability to do so depends in important respects on whether a new rule has yet taken effect. For example, new Presidents often "postpone the effective dates of certain rules that were issued at the end of the previous President's term." *Id.* at 3. During that time, new administrations can carefully review and consider whether to repeal midnight rules before they take effect. Thus, "emergency" rulemaking like that at issue here, where an agency after an election peremptorily suspends notice-and-comment to make a rule effective before Inauguration Day, risks undermining the political checks new administrations use to control such rules.

[8] In rejecting an agency's invocation of good cause, the Fifth Circuit in *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011), referenced "the APA's standard: agency action may be set aside if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not accordance with law." Nothing in the opinion, however, suggests that the Fifth Circuit applied a deferential standard of review as to the legal question of whether the good-cause standard was satisfied. Indeed, the court rejected the government's explanation as not "persuasive." *Id.* at 928. HHS's explanations for good cause here are similarly "unpersuasive," regardless of the standard of review.

EPA, 675 F.3d 917, 925 (5th Cir. 2012). An agency violates those duties when it fails to "cogently explain why it has exercised its discretion in a given manner." *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48-49 (1983).

DISCUSSION

A temporary restraining order and preliminary injunction against enforcement of the Rule are necessary because: (1) there is a substantial likelihood of success on the merits of Plaintiffs' challenges to the Rule; (2) Plaintiffs would suffer irreparable injury absent preliminary relief; (3) the balance of equities favors such relief; and (4) the public interest would not by disserved by such relief. *See Planned Parenthood of Gulf Coast, Inc. v. Gee*, 837 F.3d 477, 488 (5th Cir. 2016); *Hart v. Wells Fargo Bank, N.A.*, 2014 WL 12531172, at *1 (N.D. Tex. Mar. 31, 2014) (standard for temporary restraining order and preliminary injunction are the same).

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THEIR CHALLENGES TO THE RULE

A. HHS Lacked "Good Cause" To Promulgate The Rule Without Notice And Comment And Thus Violated The APA

The APA requires an agency seeking to promulgate a substantive rule to do so through notice-and-comment procedures. 5 U.S.C. § 553. The Medicare Act—which was invoked here by HHS—imposes the same requirements. 42 U.S.C. § 1395hh(b)(1). Under those procedures, an agency must "publish[]" a "notice of proposed rulemaking"—also called a NPRM—"in the Federal Register," and the notice must include "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). An agency must also "give

interested persons an opportunity to" submit "written data, views, or arguments." *Id.* § 553(c). After "consideration of the relevant matter presented," the agency publishes a final rule. *Id.*[9]

These requirements serve vital purposes, helping to ensure accountability and well-informed and reasoned decision-making. Congress intended "the notice and comment provisions" "'to assure fairness and mature consideration of rules.'" *Brown Exp., Inc. v. United States*, 607 F.2d 695, 701 (5th Cir. 1979). Indeed, these procedures are "one of Congress's most effective and enduring solutions to the central dilemma it encountered in writing the APA—reconciling the agencies' need to perform effectively with the necessity that the law must provide that … the regulator shall be regulated, if our present form of government is to endure." *New Jersey Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). Notice-and-comment is "especially" important "in the context of health risks" because guaranteeing a role for stakeholder participation "assure[s]" the "dialogue" "necessary" for "reasonable rules." *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980).

Congress has provided exceptions to notice-and-comment requirements, but given the requirements' importance to the rule of law, the exceptions are exceedingly "narrow[]" and "only reluctantly countenanced." *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992). An agency may dispense with the requirements for "good cause," which exists only when notice-and-comment would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B); 42 U.S.C. § 1395hh(b)(2)(C). This "exception" is "read narrowly," however, "to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed." *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985); *Texas v. United States*,

[9] The APA typically requires that a final rule may not be effective until 30 days pass from publication. 5 U.S.C. § 553(d). For certain rules, however, a separate statute—the Congressional Review Act—imposes a 60-day delay before a rule may take effect. *See id.* § 801(a)(3).

809 F.3d 134, 171 (5th Cir. 2015). Otherwise, the good-cause exception would "carve the heart out of the statute." *Action on Smoking & Health v. CAB*, 713 F.2d 795, 800-801 (D.C. Cir. 1983).

HHS's invocation of good-cause does not remotely satisfy those standards. HHS asserted that notice-and-comment would be "contrary to the public interest," as delay would "harm" patients, 81 Fed. Reg. at 90,221. In particular, HHS asserted that delay would expose patients to kidney transplant risks; additional costs of QHP coverage; and mid-year coverage disruptions. *Id.* Those purported justifications cannot be squared with the facts or law.

1. HHS's Purported Good-Cause Rationales Are Meritless

HHS's core contention that dispending with notice and comment was necessary to protect patients has things precisely backwards. Far from addressing a bona fide health-care emergency, the Rule will *create* one by decreasing patient access to transplants and precipitously exposing impecunious patients to coverage gaps and interrupting the continuity of their care—ironically, the Rule will cause the very harms it is purported to prevent. If HHS had abided by its notice-and-comment obligations, Plaintiffs and others would have explained these flaws to HHS, and presumably have averted these irrational and harmful consequences.[10]

Alleged kidney transplant risk. HHS speculates that QHPs supported by premium assistance could interfere with a patient's ability to receive a transplant because, HHS asserts, when ESRD patients "are enrolled in [QHPs] supported by third parties, they may have difficulty

[10] HHS's claims of harm are also implausible on their face. At the time HHS issued the Interim Final Rule, HHS simultaneously began a thirty-day comment period in connection with promulgating a non-interim Final Rule. Following those procedures without immediately implementing the Rule as "Interim Final" would have at occasioned a delay of only several months (assuming, of course, that the new administration agreed that such a rule was necessary). HHS does not even attempt to explain why such a delay would cause harms severe enough to justify evading notice-and-comment requirements.

demonstrating continued access to care due to loss of premium support after transplantation." 81 Fed. Reg. at 90,215. This conjecture is unsupported and irrational.

First, HHS identifies no empirical support for this purported "harm." Although charitable premium assistance may sometimes be offered only during the period when a patient is receiving dialysis treatment, an ESRD patient—who is permitted without penalty to defer Medicare enrollment when beginning dialysis treatment—is unarguably permitted to enroll in Medicare at the time of transplant and to remain on Medicare for 36 months post-transplant. 42 C.F.R. § 406.13(e)(3) (eliminating waiting period for transplant patients); Ex. C ¶ 45. There is no genuine risk, therefore, that a patient seeking a transplant cannot demonstrate that he or she can obtain continued access to care.[11]

HHS conceded this, and even *admits* that "individuals could arrange for Medicare coverage to begin at the time of transplantation." 81 Fed. Reg. at 90,215. HHS speculates that patients may not "understand their coverage options," *id.*, but that stunningly ignores that existing HHS guidance *requires* providers to make those options known and dialysis providers work with patients to do just that, *e.g.*, Seibman Decl. Ex. 5 (Fresenius Medical Care RFI Resp.) at 4-5; Ex. C ¶¶ 30-39; Ex. E ¶¶ 24-28. It was entirely unreasonable for HHS to ignore those existing requirements in assessing the issue. *See Business Roundtable v. SEC*, 647 F.3d 1144, 1150 (D.C. Cir. 2011) (SEC acted unreasonably in ignoring legal requirements in predicting how parties would act).

Second, by enabling insurers to drop coverage of QHPs, the Rule makes disruption to transplants more, not less, likely, thus relegating patients to public options in which they are

[11] After 36 months, assuming the patient is not yet eligible for Medicare due to age, the patient will be positioned to re-enter the workforce and obtain coverage through an employer group plan or on the exchange. Ex. C ¶ 45; Ex. D ¶ 82.

statistically much less likely to receive a successful transplant. There is substantial evidence—already before HHS and that Plaintiffs could have identified during notice-and-comment rulemaking—demonstrating that public options, not private insurance, hamper ESRD patients' ability to receive transplants. Ex. B ¶ 35; Seibman Decl. Ex. 2 at 18-19 & n.35-36; Seibman Decl. Ex. 6 (Kidney Care Counsel RFI Resp.) at 3. For example, instead of increasing patients' access to transplants, ESRD patients forced to shift to Medicare or Medicaid could lose their place on a transplant list if the transplant facility or provider does not accept public insurance. *See* Seibman Decl. Ex. 7 (DaVita RFI Resp.) at 6.

Certain benefits of private insurance also contribute to making a patient significantly more likely to receive a kidney transplant and experience a successful one than patients on Medicare or Medicaid. Some Medicaid plans will not pay for live transplant surgery, the type of surgery with the highest success rate. Ex. C ¶ 65. In addition, patients on public coverage may lose access to specialists necessary for them to be eligible for a transplant in the first place. Ex. B ¶ 33; Seibman Decl. Ex. 2 at 17. For example, a common reason a patient is denied a transplant is if that patient suffers from dental infections that could threaten the viability of the transplant. But patients may not have access to dental coverage on Medicare or Medicaid, increasing the risk of dental infection and thus potentially keeping patients off transplant lists. Seibman Decl. Ex. 7 at 6 & n.13; Ex. F ¶ 28.

There is thus overwhelming evidence—that HHS ignored—that patients with private insurance have greater success in obtaining transplants than those on public options, and that patients are successful (with the assistance of providers) in demonstrating continued access to care. Ex. B ¶ 35; Ex. C ¶¶ 63-66 (patients with private insurance are three times more likely to

receive a kidney than those without); Ex. D ¶¶ 50-53. HHS's contrary assertion ignores all of this.

Alleged economic costs. HHS's claim that QHPs are "financially disadvantageous for some patients with ESRD," 81 Fed. Reg. at 90,216, 90,221, also provides no basis for bypassing notice-and-comment procedures. ***First***, even if HHS's factual premise were correct (it is not), marginal *economic* cost difference for some patients between public insurance and QHPs is not an "emergency" that supports the good-cause exception. *See Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93-94 (D.C. Cir. 2012) (treating economic injury as sufficient to support good-cause exception "would give agencies 'good cause' under the APA every time a [party] in a regulated field felt a new regulation imposed some degree of economic hardship").

Second, HHS's claim of additional costs for patients is unfounded. In fact, HHS admits that "for some" patients, there are "financial benefits from [QHPs] if total premiums and cost sharing are lower," 81 Fed. Reg. at 90,216, yet HHS made *no* effort to quantify or otherwise demonstrate whether ESRD patients in the aggregate would financially benefit from being forced into Medicare coverage by the Rule. Indeed, in advancing this cost rationale, HHS ignored that many patients with QHP would experience a significant *increase* in financial costs if they were forced into public coverage. *E.g.*, Seibman Decl. Ex. 2 at 12; Ex. B ¶¶ 30-32; Ex. C ¶ 52, 68-70; Ex. E ¶ 30. For example, patients who are ineligible for Medicaid and live in a State without supplemental coverage like Medi-Gap face uncapped out-of-pocket expenses under Medicare, which could increase a patient's out-of-pocket expenses by thousands of dollars per year. *E.g.*, Seibman Decl. Ex. 9 (Dialysis Patient Citizens RFI Resp.) at 6; Ex. B ¶¶ 30-31; Ex. C ¶ 51 & fig. 1; Ex. D ¶¶ 33-36; Ex. E ¶ 30.b. Still others would be ineligible for Medicare entirely, potentially subject to paying all their healthcare costs out of pocket until they have exhausted

their savings and become Medicaid-eligible. Ex. C ¶¶ 68-69; Ex. E ¶ 30.a. Indeed, in making this argument, HHS appears to ignore more than 80 individual comments from ESRD patients making these or similar points.

The cost-based reasons HHS does offer do not withstand scrutiny. For example, HHS theorizes that for some patients Medicaid may be better because it covers out-of-pocket costs. But HHS admits that a patient enrolled in a QHP can "be enrolled in both Medicaid and individual market coverage." 81 Fed. Reg. at 90,216. HHS speculates that such an arrangement would create "financial risk" for a patient who would need to "coordinate multiple types of coverage." *Id.* But providers regularly work with their patients to ensure that patients fully understand their coverage options and how to use both forms of insurance coverage. *E.g.*, Ex. C ¶¶ 29-40 (describing DaVita's extensive patient education program, which includes dedicated teams of social workers, insurance counselors, and medical professionals); Ex. E ¶ 24-28 (similar); Ex. F ¶ 11 (similar); Seibman Decl. Ex. 6 at 13; Seibman Decl. Ex. 8 (U.S. Renal Care RFI Resp.) at 2.

With respect to Medicare patients, HHS labors to identify ways that, in certain cases, some patients might pay slightly more for a QHP because of things like late enrollment penalties. 81 Fed. Reg. at 90,216. But those are considerations on which patients can be trusted to make decisions in their self-interest, *e.g.*, Ex. C ¶ 40, and in any event hardly represent an "emergency."

Alleged mid-year coverage disruptions. HHS's final justification for abandoning notice-and-comment is that immediate implementation of the Rule is necessary to prevent "mid-year disruptions in coverage for patients/individuals who have [QHP] for which third parties make premium payments." 81 Fed. Reg. at 90,217. That rationale contradicts HHS's own findings.

Indeed, the rationale for the Rule is to drive patients to transition to public options, as HHS acknowledges would happen. *See* 81 Fed. Reg. at 90,226 (conceding the Rule will drive 50% of QHP patients receiving charitable premium assistance to public options). It is thus the Rule, not the status quo, that precipitate the very disruptive transitions between insurance coverage that the Rule claims harms consumers. *See* Ex. B ¶¶ 14-15, 37-48; Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-115; Ex. E ¶ 31, 80; Seibman Decl. Ex. 6 at 13-14.

It was entirely irrational for HHS to enact a Rule to prevent coverage disruptions when the agency knew the Rule would cause those very disruptions. Ex. B ¶ 29. HHS compounded that harm by rushing to make the Rule effective during an enrollment, knowing that many patients had already made coverage selections for the year based on an expectation that they could receive charitable premium assistance. And, if HHS were truly concerned about this risk, it could have exercised its authority over Exchanges by barring insurers from dropping coverage, at least while HHS invited notice-and-comment on these issues.[12]

2. HHS's Justifications Are Also Legally Insufficient

HHS's proffered justifications for bypassing notice-and-comment fail as a matter of law for additional reasons. ***First***, each of HHS's theories of harm reflect nothing more than anecdotes and speculation. *See* 81 Fed. Reg. at 90,224 (asserting that RFI responses "indicated that dialysis facilities *may* be encouraging patients to move from one type of coverage into another"; QHP "*may* result in harm to the individual"; and although enrollment trends are not "evidence of inappropriate behavior" they "*raise[] concerns*" of steering) (emphases added).

[12] That "[t]his is the time of year when patients often make enrollment decisions, with Open Enrollment in the individual market ongoing and General Enrollment Period in Medicare about to begin on January 1," 81 Fed. Reg. at 90,221, adds nothing to HHS's good-cause analysis. HHS controls the timing of the enrollment periods and HHS's announcement of the Rule and implementation on an expedited basis near the enrollment period has in fact caused immeasurable confusion and concern among ESRD patients. Ex. B ¶ 49; Ex. D ¶¶ 110-114.

Such "speculation is" ordinarily "an inadequate replacement for the agency's duty to undertake … reasoned analysis." *Horsehead Resource Development Co., Inc. v. Browner*, 16 F.3d 1246, 1269 (D.C. Cir. 1994) (per curiam). And that is particularly so under the good-cause exception: fear a problem "*could*" occur might prompt a "[c]ause for concern," but "hardly" demonstrates a "crisis" sufficient to bypass notice-and-comment. *Sorenson Commc'ns*, 755 F.3d at 706-707.

Second, the problems identified by the Rule do not amount to an emergency sufficient to constitute "good cause" as a matter of law. The "public interest" prong of the exception—the only one invoked by HHS—is "rare[ly]" satisfied, *Mack Trucks*, 682 F.3d at 94, and the justifications offered by HHS do not remotely satisfy that standard. Even were HHS correct that the Rule would in fact provide some health or financial benefits to ESRD patients, that would not excuse bypassing notice-and-comment. "[T]he bare need to have regulation" is not good cause. *Marshall*, 628 F.2d at 621. Most, "if not all," agency rules "are designed to eliminate some real or perceived harm. If the mere assertion that such harm … were enough to establish good cause, then notice and comment would always have to give way." *United States v. Reynolds*, 710 F.3d 498, 512 (3d Cir. 2013). Indeed, the "argument could as easily be used to justify immediate implementation of any sort of health or safety regulation, no matter how small the risk for the population at large or how long-standing the problem." *American Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 401 (D.D.C. 1983).[13] Thus, Plaintiffs are likely to success on their claim (set forth in Count I of the Complaint), that all of HH's purported justifications for emergency rulemaking fail, and the Interim Final Rule must be vacated for that reason.

[13] Of course, these limited health-related gains are not HHS's true purpose in promulgating the Rule. Instead, HHS reveals its true motivations in a footnote: it acknowledges that it could address the purported problem of insurers dropping coverage by "requiring issuers to accept [third-party] payments," but it asserts that result "would destabilize the individual market risk pool." 81 Fed. Reg. at 90,218; *see also id.* at 90,226 (rejecting such a requirement as an alternative to the rule, under the same reasoning).

Furthermore, as evidenced by OIG's decades-old opinion as well as more recent guidance issued by HHS, questions of charitable donations and third-party premium assistance have long been on HHS's radar. This is thus decidedly not a case in which an agency faces an a new or escalating threat, and invokes the good-cause exception to head off or respond to that emergency. *See Hawaii Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (finding good cause based on "recent escalation of fatal air tour accidents"); *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (finding good cause to change rules following 9/11).

Thus, in the end, the only true "emergency" HHS faced here was a political one: it wanted to put its regulation into effect before Inauguration Day. But an election and orderly transition of power obviously do not provide good cause for dispensing with basic legal requirements of reasoned rulemaking.[14]

B. The Rule Is Arbitrary And Capricious

For the reasons explained above, HHS's failure to follow notice-and-comment procedures without good cause requires vacatur of the Rule. Independently, Plaintiffs are likely to prevail on their challenges to the Rule as arbitrary and capricious. 5 U.S.C. § 706(2)(A); *see, e.g.*, *American Acad. of Pediatrics*, 561 F. Supp. at 399 (applying arbitrary-and-capricious

[14] That HHS invited "post-promulgation comments" on the Interim Final Rule and a final rule does not "excuse compliance with APA procedures." *Johnson*, 632 F.3d at 929; *accord Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012); *Marshall*, 628 F.3d at 621-622. Nor is the APA violation harmless. Plaintiffs' submissions make clear "they can mount a credible challenge to the [Rule] and were thus prejudiced by the absence of an opportunity to do so before" HHS issued the Rule. *Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 754 (2001). And the RFI is no substitute for an NPRM. An NPRM must "describe the range of alternatives being considered with reasonable specificity," *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983), so that stakeholders can respond with an "adversarial critique of the agency," *HBO, Inc. v. FCC*, 567 F.2d 9, 55 (D.C. Cir. 1977). Nothing about the RFI fulfilled those objectives. The RFI was "issued solely for information and planning purposes," 81 Fed. Reg. 57,555, and did not set forth a proposed rule on which to comment.

review to interim HHS rule issued without notice-and-comment); Compl. ¶¶ 127-149. Given the emergency nature of Plaintiffs' request for preliminary relief, and the clear illegality of HHS's evasion of notice-and-comment, Plaintiffs address these substantive challenges only briefly, and reserve the right, of course, to develop them more fully in further proceedings in this litigation.

First, HHS irrationally ignored the disadvantages of the Rule. "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2016). Here, HHS based the Rule on the supposed benefits of driving ESRD patients from QHPs to Medicare/Medicaid coverage. *See* 81 Fed. Reg. at 90,217; Ex. B ¶ 16. Before putting into motion such a consequential chain of events, however, reasoned decision-making required HHS to acknowledge the *benefits* of QHPs for some patients and weigh the advantages and disadvantages of its Rule.

Numerous responses to the RFI detailed the benefits of QHPs. For example, individual patients and others explained that many patients have *lower* costs under QHPs than public options. *E.g.*, Seibman Decl. Exs. 10-16 (Patient RFI Resps.); *see* Seibman Decl. Ex. 2 at 12-18; Seibman Decl. Ex. 17 (Kidney Care Partners RFI Resp.) at 4-5. In addition, patients explained that, unlike QHPs, Medicare's out-of-pocket costs are not capped, and many have no way to cover those costs, either because they live in a State without supplemental coverage like Medi-Gap or because they are not eligible for Medicaid. *E.g.*, Seibman Decl. Ex. 14. Inexplicably, HHS ignored the substance of those comments, focusing entirely on the "potential harm to patients" in justifying the Rule and making no effort to judge whether QHP benefits outweighed

those harms. *See* 81 Fed. Reg. at 90,215-90,217. It was irrational to adopt a Rule purportedly aimed at helping patients without weighing the *disadvantages* as well as benefits of the Rule.[15]

Second, the risk that the Rule would lead to unlawful discrimination by insurers was quite obviously an "an important aspect of the problem," *State Farm*, 463 U.S. at 43, that HHS was required to, but did not, address. The ACA prohibits covered insurers from discriminating on several prohibited bases, incorporating by reference provisions from federal anti-discrimination law. *See* 42 U.S.C. § 18116; 45 C.F.R. § 92.101. Insurers' refusal to accept charitable assistance from ESRD patients violates that mandate on at least two prohibited bases—disability and race, because ESRD is a disability protected under the statute and ESRD patients are disproportionally racial minorities, as RFI responses made clear. *E.g.*, Seibman Decl. Ex. 5 at 11-13. Insurers who drop coverage of ESRD patients as a result of the Rule will thus do so in violation of these non-discrimination requirements.[16]

In addition, HHS was obligated—but failed—to consider the significant problem that the Rule enables coverage denials based on pre-existing conditions. The ACA prohibits insurers from imposing eligibility rules based on that basis, *see* 42 U.S.C. § 300gg-4(a), but those who receive charitable assistance are usually those who need it because of an existing health

[15] HHS did reference that it received over 600 comments in a "letter-writing campaign" from patients receiving premium assistance from Patient Services, Inc. (PSI), an organization that provides support to patients with a range of chronic diseases. But none of those patients were dialysis patients because dialysis patients do not qualify for PSI assistance. Approximately 80 individual patients, in their own words (not through a form letter), expressed satisfaction with QHPs. HHS's cursory dismissal of those patient letters was indefensible.

[16] HHS asserts that the Rule "does not alter" requirements relating to "guaranteed availability" or "non-discrimination-related regulations," 81 Fed. Reg. at 90,220, but it does not even attempt to explain how insurers could comply with those requirements while also dropping coverage after learning of premium payments through the Rule's insurer disclosure requirements.

condition (whether ESRD, HIV/AIDS, or something else). Ex. B ¶ 7-8; Ex. D ¶¶ 56-66, Ex. E ¶ 37. HHS wholly ignored this important issue in promulgating the Rule.

Third, HHS unreasonably departed from decades-old guidance without acknowledging or justifying the break with precedent. Although an agency may change its position, the APA "ordinarily demands[] that [the agency] display awareness that it *is* changing position." *FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009). Thus, "[a]n agency may not … depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *Id.* HHS disregarded those requirements here. As noted above, in 1997, HHS OIG issued an opinion allowing AKF to operate HIPP while permitting providers to join the thousands of donors supporting AKF and other charities. The opinion recognized the value of premium assistance in enhancing patient choice and it set forth guidelines expressly aimed at ensuring that donors would be walled from HIPP's operations and to prevent undue influence or patient steering in selecting a provider. *See* Seibman Decl. Ex. 3. The guidance has successfully governed charitable giving in this context for almost two decades. *See* Ex. D ¶¶ 96-102; Seibman Decl. Ex. 5 at 8.

The Rule abruptly breaks from that longstanding precedent. Under OIG precedent, charitable premium assistance by AKF was legitimate and lawful. The Rule, however, permits and encourages insurers to *reject* charitable assistance that complies with OIG guidance. Indeed, in the wake of the Rule's announcement, insurers are doing just that. *E.g.*, Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-107; Ex. E ¶ 61 (describing letter received from Blue Cross Blue Shield of Minnesota stating that third-party premium assistance is not permitted for "fully-insured commercial lines of business, including individual/family plans and group plans"). Moreover, as discussed above, the Rule breaks with OIG guidance in other ways, for example, by forcing providers to make

disclosures that violate longstanding OIG-imposed requirements in this area. Ex. C ¶¶ 94-101; Ex. E ¶¶ 70-74. HHS's failure to display "awareness" it was "changing [its] position" from its longstanding guidance requires vacatur of the Rule. *Fox Television Stations*, 556 U.S. at 515.

II. THE RULE WILL IRREPARABLY HARM PLAINTIFFS

Preliminary relief is also appropriate and necessary because Plaintiffs are "likely to suffer irreparable harm, that is, harm for which there is no adequate remedy at law." *Daniels Health Scis., LLC v. Vascular Health Scis., LLC*, 710 F.3d 579, 585 (5th Cir. 2013).

A. Individual Patients Will Suffer Irreparable Harm

Patients—whose interests are represented by DPC, *see Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 286 (5th Cir. 1999) (entity can represent patient interests); *Oak Park Health Care Ctr., LLC v. Johnson*, 2009 WL 331563, at *3 (W.D. La. Feb. 10, 2009) (same)—face irreparable injury in at least two ways.

First, although the Rule ostensibly seeks to protect ESRD patients, it in fact exposes patients to serious and immediate health risks by forcing a transition exclusively to public coverage, as demonstrated above. *See supra* pp. 18-19 (explaining how the Rule will drive patients off QHPs); *see also* Ex. B ¶¶ 14-15, 37-48; Ex. C ¶¶ 90-91; Ex. D ¶¶ 105-115; Ex. E ¶¶ 31, 78. For example, for patients who are compelled to switch to Medicaid only, there is a severe shortage of Medicaid providers—especially in rural areas and among specialists—which can jeopardize care for ESRD patients. Ex. B ¶ 33; Ex. C ¶ 58; Ex. D ¶¶ 37-38; Ex. E ¶ 30.f. "Only 67% of primary care providers treat Medicaid patients, and only 44% of those providers accept new Medicaid patients." Ex. C ¶ 58. Thus, under the Rule, patients may not be able to find specialists in the Medicaid network close by, or if they can, there can be unreasonable waits

to get an appointment. For dialysis patients, this lost time can have a significant impact on health. Ex. D ¶¶ 43-45, Ex. E ¶ 83.

There are equally serious access-to-care risks for patients forced to switch to Medicare. Not all ESRD patients qualify for Medicare, due to duration-of-work requirements or citizenship requirements, and under the Rule those individuals would lose access to any insurance option in perpetuity. Ex. C ¶¶ 17, 49-50 (over 1,000 DaVita patients ineligible for either Medicare or Medicaid); Ex. E ¶ 32; Ex. F ¶ 17 (approximately 310 U.S. Renal Care patients are ineligible for either Medicare or Medicaid). Without dialysis ESRD patients risk a serious medical setback, even death. Ex. B ¶¶ 3-4; Ex. C ¶ 9; Ex. E ¶ 81. "No harm could be more irreparable." *Knowles v. Horn*, 2010 WL 517591, at *7 (N.D. Tex. Feb. 10, 2010); *see also Int'l Res., Inc. v. N.Y. Life Ins. Co.*, 950 F.2d 294, 302 (6th Cir. 1991) (loss of health insurance, which would "adversely effect the proper maintenance of [plaintiff's] health," as well "interruption of the care might cause irreversible physical harm," was sufficient to establish irreparable harm).

In addition, Medicare does not extend to family members, and most households with an individual suffering ESRD lack financial resources to afford private insurance for other household members. QHPs may provide such coverage. Ex. B ¶ 34; Ex. C ¶ 55; Ex. D ¶¶ 31-32, 39-40; Ex. E ¶ 30. Thus, under the Rule, those family members would be left without *any* health insurance—which is also irreparable harm. *See United Steelworkers of America v. Ft. Pitt Steel Casting, Div. of Conval–Penn, Inc.*, 598 F.2d 1273, 1280 (3d Cir. 1979) (possible denial of "adequate medical care as a result of having no insurance would constitute 'substantial and irreparable injury"); *Whelan v. Colgan*, 602 F.2d 1060, 1062 (2d Cir. 1979) ("threatened termination of … medical coverage for workers and their families obviously raised the spectre of

irreparable injury"); *United Steelworkers of America v. Textron, Inc.*, 836 F.2d 6, 8 & 9 (1st Cir. 1987) (similar).

Second, patients will be irreparably harmed by the loss of *choice* of coverage. *See* Ex. D ¶¶ 20-29, 71, 84, 105-115. Patient choice is a cornerstone of the ACA, 42 U.S.C. § 18032, and Congress has long recognized the right of ESRD patients to remain on private insurance for certain periods of time, 42 U.S.C. § 426-1(a); *see also* Ex. B ¶¶ 18-28; Ex. C ¶ 14. The Rule countermands those judgments by steering patients exclusively to public coverage, even when a patient would prefer private coverage. That deprivation of choice is irreparable harm. *See Planned Parenthood of Gulf Coast, Inc. v. Gee*, 837 F.3d 477, 501 (5th Cir. 2016) (denial of "access to a much needed medical provider and the legal right to the qualified provider of their choice" is "irreparable harm").

B. Provider Plaintiffs Will Suffer Irreparable Harm

Absent preliminary relief, Provider Plaintiffs will also suffer multiple types of irreparable injury. ***First***, the Rule likely will lead to dialysis-facility closure. The cost of treating patients covered by public insurance is often more than the reimbursement received from the government for that treatment. Dialysis providers are able to remain in business largely because the reimbursements they receive from private insurers are sufficient to make provision of care to all patients, including those covered by public insurance, financially viable. Because of the Rule, however, many ESRD patients receiving private insurance will switch to public insurance. This will cause at least some of Plaintiff Providers' facilities to become financially unsustainable, potentially leading to facility closures, employee lay-offs, and harm to the vulnerable patients who will need to travel significant distances to receive treatment multiple times per week. Ex. C ¶¶ 73-77 (six majority-owned DaVita facilities in Texas may close); Ex. E ¶¶ 69, 82-84 (at least

two FMCNA facilities in the Eastern District of Texas, which treat approximately 170 patients, may close); Ex. F ¶¶ 52-53, 60-62. These harms are irreparable. *See Texas v. EPA*, 829 F.3d 405, 434 (5th Cir. 2016) ("unemployment and the permanent closure of plants" are "irreparable" harms); *Planned Parenthood of Cent. N. Carolina v. Cansler*, 804 F. Supp. 2d 482, 499 (M.D.N.C. 2011) (similar).

Second, the Rule risks catastrophic economic injury resulting from termination from Medicare. Given the complexity, uncertainty, and inconsistency of the Rule as well as the unrealistic timeline for implementation, although Provider Plaintiffs will work hard to comply, there is a significant risk they will be unable to do so. Ex. C ¶¶ 82-106 (explaining four reasons why compliance will be challenging); Ex. E ¶¶ 51-62, 64; Ex. F ¶ 51. Under the Medicare Act and HHS rules, the default sanction for non-compliance with a CfC is termination from Medicare. 42 U.S.C. § 13955rr(g), 42 C.F.R. § 488.604. Termination would be financially ruinous for providers, *e.g.*, Ex. C ¶¶ 78-81 (termination would "risk[] insolvency"); Ex. E ¶¶ 69, 82-84; Ex. F ¶¶ 52-53, and the risk of such catastrophic economic harm is irreparable injury, *see Humana, Inc. v. Avram A. Jacobson, M.D., P.A.*, 804 F.2d 1390, 1394 (5th Cir. 1986) (affirming irreparable-harm finding because "[l]oss of Medicare funding would directly deprive [plaintiff] of more than 50% of its business"); *New Orleans Home for Incurables, Inc. v. Greenstein*, 911 F. Supp. 2d 386, 408 (E.D. La. 2012).

Third, significant and substantial compliance costs—which cannot be recovered later from the government—are also irreparable. *See American Health Care Ass'n v. Burwell*, 2016 WL 6585295, at *15 (N.D. Miss. Nov. 7, 2016) (considering compliance costs as part of irreparable injury analysis); *Nevada v. United States Dep't of Labor*, 2016 WL 6879615, at *7 (E.D. Tex. Nov. 22, 2016) (same). The Rule will compel significant changes to Provider

Plaintiffs' operations, and impose substantial costs, particularly given the compressed thirty-day compliance schedule. Ex. C ¶¶ 107-110 ($11 million in compliance costs for DaVita); Ex. E ¶¶ 50-59; Ex. F ¶¶ 54-57; *see* 81 Fed. Reg. at 90,225 (estimating compliance costs of more than $29 million annually).[17] These injuries are, by definition, irreparable because "[n]o mechanism … exists for the [plaintiffs] to recover the compliance costs they will incur if the [challenged] [r]ule is invalidated on the merits." *Texas v. EPA*, 829 F.3d at 434; *Planned Parenthood Gulf Coast, Inc. v. Kliebert*, 141 F. Supp. 3d 604, 650 (M.D. La. 2015) (similar).

Finally, the Rule risks serious reputational injury to Provider Plaintiffs and interference with their business relationships. Because the Rule applies only to providers who donate to organizations that provide third-party assistance, the Rule may drive patients to other providers not covered by the Rule, so they can keep their QHP coverage. Ex. C ¶¶ 112-113; Ex. F ¶ 70. The Rule also compels providers to disclose private details about how patients are paying for their insurance; thus, patients will lose QHP coverage, and they may blame their provider for this result, damaging Providers' reputations and undermining goodwill. Ex. C ¶¶ 114-115; Ex. F ¶¶ 68-71. Provider Plaintiffs will also suffer reputational harm if facilities are terminated for non-compliance with the CfCs imposed by the Rule. Ex. E ¶¶ 64-68. Those harms are all irreparable. *E.g.*, *Humana*, 804 F.2d at 1394 (interference with patient relationships is irreparable harm); *Kliebert*, 141 F. Supp. 3d at 650 ("reputation[al] harm" was irreparable).

III. THE BALANCE OF EQUITIES SUPPORTS PRELIMINARY RELIEF

Preliminary relief is also necessary because the "threatened injury outweighs the harm to [HHS]." *Gee*, 837 F.3d at 488. Here, the balance of equities weighs decisively in favor of

[17] Compounding the compliance problems, the Rule poses a dilemma, requiring providers to attempt to comply with the seemingly contradictory requirements of the Interim Final Rule and longstanding OIG guidance. Ex. C ¶¶ 94-101; Ex E. ¶¶ 70-74; Ex. F ¶¶ 45-46.

preliminary relief. As explained above, Plaintiffs will suffer concrete and irreparable injury if the Rule takes effect. On the other side of the ledger, HHS would suffer no comparable harm were the Rule—which will substantially disrupt the status quo—delayed while the Court resolves Plaintiffs' claims. *See American Health Care Ass'n*, 2016 WL 6585295, at *18 ("balance of the harms … [is] determined partly in terms of whether it would be better to give the courts an opportunity to consider the merits of a Rule which sharply alters the pre-existing status quo, before it goes into effect"). Harm to HHS is further minimized by the fact that HHS is currently conducting a rulemaking on these issues that may result in implementation of these or similar regulations in a few months, provided HHS considers them appropriate in the light of comments and further consideration. Thus, "the threatened injury [to Plaintiffs] if the injunction is denied outweighs any harm that will result if the injunction is granted." *Texas*, 809 F.3d at 186.

IV. PRELIMINARY RELIEF IS IN THE PUBLIC INTEREST

Finally, preliminary relief "will not disserve the public interest." *Gee*, 837 F.3d at 489. To the contrary: the public interest strongly favors such relief to preserve the status quo.

First, the public interest lies in ensuring that ESRD patients have access to insurance coverage options of their choice, regardless whether they receive support for their premiums. *See Gee*, 837 F.3d at 502 ("public interest weighs in favor of … allowing some of the state's neediest individuals to continue receiving medical care from a much needed provider"). The serious risks and substantial confusion created by the Rule with respect to access to care are reason enough to enjoin the Rule pending judicial review. Ex. D ¶¶ 110-114.

Second, there is a strong "public interest" in ensuring that "government agencies be enjoined from acting in a manner contrary to law." Order Granting Preliminary Injunction 30, *Assoc. Builders & Contractors of SE Tex. v. Rung*, No. 1:16-cv-00425-MAC, Dkt. #22 (E.D.

Tex. Oct. 24, 2016). For that reason, courts in this Circuit regularly grant relief to preserve the status quo pending judicial review of agency rules. *See, e.g.*, *Nevada*, 2016 WL 6879615, at *8; *American Health Care Ass'n*, 2016 WL 6585295, at *18; *Texas v. United States*, 2016 WL 4426495, at *17 (N.D. Tex. Aug. 21, 2016). Here, HHS made a deliberate choice to bypass the APA, for the political goal of tying the hands of a future Presidential administration. Sanctioning such gamesmanship would disserve the public interest and provide a road map for future conduct by government agencies. Moreover, requiring HHS to engage in the notice-and-comment period contemplated by the APA before regulating in this area will ensure more reasoned decision-making permitting fair consideration of all competing concerns that would presented to HHS during a rulemaking.

V. THIS COURT HAS JURISDICTION

This Court has jurisdiction over this dispute. Because HHS has argued that review of rulemaking is available only through the agency appeal process, 42 U.S.C. §§ 405(g), (h). Any such jurisdictional objection would fail here for at least two reasons.

First, the Supreme Court has recognized that federal-question jurisdiction under 28 U.S.C. § 1331 remains available "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (2000). That exception applies where, as here, "plaintiffs can show there is no way of having their claims reviewed" or "there exists a 'serious practical roadblock' to having the[] claims reviewed in any capacity, administratively or judicially." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012).

Patients and DPC have *no* administrative means to challenge CfCs or the Rule, and thus have "no way of having their claims reviewed." *Physician Hosps. of Am.*, 691 F.3d at 655. By

definition, patients affected by the Rule are those who receive insurance premium assistance *outside* of Medicare, and they have no Medicare remedy. And patients have unique and, in many ways distinct, interests from others affected by the Rule given the life-threatening implications that will result from the Rule's disruptions to access to care. Section 1331 jurisdiction exists in such cases. *E.g.*, *Furlong v. Shalala*, 238 F.3d 227, 234 (2d Cir. 2001); *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 711-714 (D.C. Cir. 2011).

Provider Plaintiffs also have no genuine recourse to agency review, and therefore may invoke jurisdiction under § 1331 to challenge the Rule. Although providers could theoretically violate the Rule and the challenge the Rule's legality in lengthy and multi-layered administrative proceedings—they would face "serious practical roadblock[s]" to pursuing that option. The default sanction for violating a CfC is Medicare termination. 42 U.S.C. § 13955rr(g), 42 C.F.R. § 488.604. Thus, any provider seeking administrative review would risk "termination from the Medicare program," which is such a "draconian sanction"—equivalent to "economic suicide"—that such an administration option, courts have held, amounts to "no review at all." *Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 38-39 & n.4 (D.D.C. 2000); *American Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23, 29 (D.D.C. 2002) (similar); *see* Ex. C ¶¶ 78-81; Ex. E ¶¶ 12, 64-69, 83; Ex. F ¶ 43. Indeed, the Supreme Court held that an analogous scheme did not provide "a meaningful avenue of relief" because it "require[d] plaintiffs to bet the farm … [to] test[] the validity of the law." *Free Ent. Fund v. Public Co. Acctg. Oversight Bd.*, 561 U.S. 477, 490-91 (2010) (citations omitted).

Second, this Court has mandamus jurisdiction under 28 U.S.C. § 1361. "[Section] 405(h) does not preclude mandamus jurisdiction." *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 765 (5th Cir. 2011). Mandamus is available "when (1) the plaintiff has a clear right to

relief, (2) the defendant a clear duty to act, and (3) no other adequate remedy exists." *Id.* at 768. Those standards are satisfied here, at least with respect to Plaintiffs' notice-and-comment claim. Plaintiffs have a clear right to enforce HHS's non-discretionary duty to follow notice-and-comment procedures, and no other remedy exists because it would be legally or practically impossible and futile to pursue that objection through an administrative process, where no subordinate HHS official could compel compliance with APA requirements.

CONCLUSION

The Court should enter a temporary restraining order and preliminary injunction against enforcement of the Rule.

Dated: January 6, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Emergency Motion for Temporary Restraining Order and Preliminary Injunction has been served by certified mail on the following, this 6th day of January, 2017:

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CERTIFICATE OF CONFERENCE

I hereby certify that Plaintiffs have complied with the meet and confer requirement in Local Rule CV-7(h). David Ogden, Kelly Dunbar, and Stephen Carey, counsel for Plaintiff DaVita Inc., conferred with Peggy Dotzl, Acting General Counsel for Defendant Department of Health and Human Services, via telephone on January 5 and 6, 2017, and spoke with Joel McElvain, Assistant Branch Director for the Federal Programs Branch of the U.S. Department of Justice, via telephone on January 6, 2017, regarding the Plaintiffs' Emergency Motion for Temporary Restraining Order and Preliminary Injunction and Request for Oral Argument and Expedited Consideration. Counsel for Defendants stated that the Defendants opposed the requested injunction. The discussions conclusively ended in an impasse, leaving an open issue for the court to resolve. LR CV-7(i).

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